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| APPLICATION NO.              | FILING DATE                     | FIRST NAMED INVENTOR               | ATTORNEY DOCKET NO. | CONFIRMATION NO |
|------------------------------|---------------------------------|------------------------------------|---------------------|-----------------|
| 10/517,788                   | 12/14/2004                      | Jacobus Alphonsus Josephus Van Dun | JAB-1712-USNP       | 8615            |
| 27777                        | 7590 12/12/2005                 |                                    | EXAMINER            |                 |
| PHILIP S. J                  |                                 |                                    | RAHMANI, NILOOFAR   |                 |
| JOHNSON &<br>ONE JOHNS       | : JOHNSON<br>ON & JOHNSON PLAZA |                                    | ART UNIT            | PAPER NUMBER    |
| NEW BRUNSWICK, NJ 08933-7003 |                                 |                                    | 1625                |                 |

DATE MAILED: 12/12/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

|  | Application No.   | Applicant(s)   |
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|  |   |  |
| Office Action Summan   | 10/517,788  | VAN DUN ET AL.   |
| Office Action Summary  | Examiner  | Art Unit   |
|  | Niloofar Rahmani  | 1625   |
| The MAILING DATE of this communication app<br>Period for Reply   | pears on the cover sheet with the c   | orrespondence address  |
| A SHORTENED STATUTORY PERIOD FOR REPLY WHICHEVER IS LONGER, FROM THE MAILING DA  - Extensions of time may be available under the provisions of 37 CFR 1.1: after SIX (6) MONTHS from the mailing date of this communication.  - If NO period for reply is specified above, the maximum statutory period v  - Failure to reply within the set or extended period for reply will, by statute Any reply received by the Office later than three months after the mailing earned patent term adjustment. See 37 CFR 1.704(b).  | ATE OF THIS COMMUNICATION 36(a). In no event, however, may a reply be timwill apply and will expire SIX (6) MONTHS from a cause the application to become ABANDONE      | N. nely filed the mailing date of this communication. D (35 U.S.C. § 133). |
| Status   |   |  |
| Responsive to communication(s) filed on 14 Decay This action is FINAL.  2b) ☐ This 3) ☐ Since this application is in condition for allower closed in accordance with the practice under Expression in the practice of th | action is non-final.  nce except for formal matters, pro  | ,  |
| Disposition of Claims  |   |  |
| 4) Claim(s) 1-12 is/are pending in the application.  4a) Of the above claim(s) is/are withdray.  5) Claim(s) is/are allowed.  6) Claim(s) is/are rejected.  7) Claim(s) is/are objected to.  8) Claim(s) 1-12 are subject to restriction and/or of the specification is objected to by the Examine 10) The drawing(s) filed on is/are: a) according and applicant may not request that any objection to the Replacement drawing sheet(s) including the correct 11) The oath or declaration is objected to by the Examine 10.   | wn from consideration.  election requirement.  er.  epted or b) objected to by the I drawing(s) be held in abeyance. Section is required if the drawing(s) is objected. | e 37 CFR 1.85(a).<br>jected to. See 37 CFR 1.121(d).                       |
| Priority under 35 U.S.C. § 119   | •   |  |
| 12) Acknowledgment is made of a claim for foreign a) All b) Some * c) None of:  1. Certified copies of the priority document: 2. Certified copies of the priority document: 3. Copies of the certified copies of the priority document: application from the International Bureau * See the attached detailed Office action for a list   | s have been received. s have been received in Applicati rity documents have been receive u (PCT Rule 17.2(a)).  | on No ed in this National Stage  |
|  |   |  |
| Attachment(s)  |   | :  |
| 1) Notice of References Cited (PTO-892) 2) Notice of Draftsperson's Patent Drawing Review (PTO-948) 3) Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date   | 4) Interview Summary Paper No(s)/Mail Do 5) Notice of Informal P 6) Other:  |  |

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## **DETAILED ACTION**

1. Claims 1-12 are currently pending in the instant application.

## **Priority**

2. This application is a 371 of PCT/EP03/50276, filed on 06/30/2003, which claims benefit of 60/393,149 filed on 07/02/2002.

## 3. Election/Restrictions

Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions, which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

Claim 7 is non-statutory "use" claim, which is withdrawn from consideration.

Because of withdrawn from consideration, these claims are put in the lack of unity groups. Cancellation is recommended.

I. Claims 1-6, and 8, drawn to compound, pharmaceutical composition, method of making, and method of using of formula (I), classified in class various, subclass various. If this group is elected, a further election of a single disclosed species of compound is also required. Further restriction based on the species election may be required.

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II. Claims 9-10, drawn to compound from Micromonospora spp JS 1035 deposit No LMG P-12525, classified in class various, subclass various. If this group is elected, a further election of a single disclosed species of compound is also required. Further restriction based on the species election may be required.

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III. Claim 11, drawn to microorganism wherein deposited under deposit No. LMG P-12525, classified in class various, subclass various. If this group is elected, a further election of a single disclosed species of compound is also required. Further restriction based on the species election may be required.

IV. Claim 12, drawn to microorganism wherein deposited under deposit No. LMG P-12526, classified in class various, subclass various. If this group is elected, a further election of a single disclosed species of compound is also required. Further restriction based on the species election may be required.

The inventions listed as Groups I and IV do not relate to a single general inventive concept under 35 USC 121 or PCT Rule 13.1 because:

**PCT Rule 13.1** states that the international application shall relate to one invention only or to a group of inventions so linked as to form a single general inventive concept ("requirement of unity of invention").

**PCT Rule 13.2** states that the unity of invention referred to in Rule 13.1 shall be fulfilled only when there is a technical relationship among those inventions involving one or more of the same or corresponding special technical features.

Annex B, Part 1(a), indicates that the application should relate to only one invention, of if there is more than one invention, inclusion is permitted if they are so slinked to form a single general inventive concept.

Annex B **Part 1(b)**, indicates that "special technical features" means those features that as a whole define a contribution over the prior art.

Annex B **Part 1(c)**, further defines independent and dependent claims. Unity of invention only is concerned in relation to independent claims. Dependent claims are defined as a claim that contains all the features of another claim and is in the same category as the other claim. The category of a claim refers to the classification of claims according to subject matter e.g. product, process, use, apparatus, means, etc.

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Annex B Part 1(e), indicates that the permissible combinations of different categories of claims. Part 1(e)I, states that inclusion of an independent claim for a given product, an independent claim for a process specially adapted for the manufacture of the said product, and an independent claim for a use of the said product is permissible.

Annex B, Part 1(f), indicates the "Markush practice" of alternatives in a single claim. Part 1(f)I, indicates the technical relationship and the same or corresponding special technical feature is considered to be met when (A) all alternatives have a common property or activity, and (B) a common structure is present or al alternatives belong to a recognized class of chemical compounds. Further defining (B), Annex B, Part 1(f)(I-iii), the common structure must; a)

occupy a large portion of their structure, or b) the common structure constitutes a structurally distinctive portion, or c) where the structures are equivalent and therefore a recognized class of chemical compounds, each member could be substituted for one another with the same intended result. That is, with a common or equivalent structure, there is an expectation relationship and the corresponding special technical feature result from a common (or equivalent) structure that is responsible for the common activity (or property). Part 1(f) iv, indicates that when all alternatives of a Markush grouping can be differently classified, it shall no, take alone, be considered justification for finding a lack of unity. Part 1(f)v, indicates that "When dealing with alternatives, if it can be shown that at least *one* Markush alternative is not novel over the prior art, the question of unity of invention shall be reconsidered by the examiner"

In the instant case, at least one Markush alternative is not novel because prior art by EP 0689839 anticipated group I, thus the lacking of unity of invention has been found.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

**4.** Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be

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accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Niloofar Rahmani whose telephone number is 571-272-4329. The examiner can normally be reached on Monday through Friday from 8:30 am to 5:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Cecilia Tsang, can be reached on 571-272-0562. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <a href="http://pair-direct.uspto.gov">http://pair-direct.uspto.gov</a>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

NILOOFAR RAHMANI

PRIMARY EXAMINER

GARET SEAMAN

11/30/2005

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NR